

R E M A R K S

The Rejection of April 15, 2004 has been reviewed and its contents carefully noted. Reconsideration of this case, as amended, is respectfully requested. Applicants thank the Examiner for his thorough and detailed remarks in the most recent Office Action. More specifically, Applicants thank the Examiner for his substantial effort in trying to move the claims to allowance given the prior art. Claims 1-6 and 10-70 are currently pending. Claims 1, 11, 47-52, 55 and 57-64, 13-20, 24-31, 35-42 and 47-55 are amended herein. Claims 7-9 canceled herein. Claim 71 has been added herein.

Priority Claim

The current application was filed on August 6, 2003 as a utility filing and does not rely on any prior patent or patent application for its priority date. Therefore, Applicant is in compliance with 35 USC § 119(e), and any objection based thereon is respectfully overcome.

Changes to Specification & Figures

On those pages that had open blocks of space the above amendments have attempted to indicate that the space was left open due to word processing and graph placement issues. No new text or additional text is to be entered. Appropriate changes have been made. However, this along with the fact that the Examiner has noted and objected to the presence of informational graphs within the text of the specification has made necessary a large volume of changes to the specification that in some cases effects page-to-page content and numbering. The graphs objected to were placed in the text for reference purposes and have now been deleted and re-inserted as figures in the specification in an attempt to comply with the Examiner's wishes. No new matter has been added. With these changes the overall flow of the specification has been significantly altered. If the Examiner can provide any suggestions as to how this process could

be streamlined or made such that the corresponding changes to the application are minimized the Applicants would be grateful.

The Rejection Under 35 U.S.C. §112, first paragraph

The Applicants note that the Examiner cited 35 USC § 112, first paragraph but provide no rejections based on this section. Therefore, Applicants are confused as to the purpose and respectfully ask for clarification. It is believed that the claims, as amended overcome any objection under 35 U.S.C. §112, first paragraph.

The Rejection Under 35 U.S.C. §112, second paragraph

Claims 1-70 were rejected by the Examiner under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point and distinctly claim the invention. With substantial amendments to the only independent claim, claim 1, this rejection is traversed.

Applicants also note that the Examiner has stated that claim 1 includes terms that are not fully explained within the specification. Applicants respectfully disagree and point to p. 16 lines 3-11 and p. 17 lines 9-20 for explanation of the process methodology meant by the language “transition point flux” and “pressure dependent region” of a curve and “the transition point of the filtration.” It should also be noted that the current invention is one that uses graphic information and to determine what set of conditions are optimal for various ultrafiltration steps and consequent recovery of the protein of interest.

Respectfully, the Examiner is also reminded that the Inventor is allowed “to be his own lexicographer,” and that if this verbal license leads to any ambiguity the claims are to be construed “in connection with the other parts of the..patent application.” Autogiro Co. of America v. United States, 384 F.2d 391 (Ct. Cl. 1967).

As to claims 2 and 12-17, respectfully, the Examiner is reminded that the recitations of claim 1 entail positive steps and methods for the desired filtration process. This overcomes any rejection of the claims for not including such steps.

Claims 1, 11, 47-52, 55 and 57-64, 13-20, 24-31, 35-42 and 47-55 were amended herein to reflect the Examiner's concerns, and now are believed to comply with the provisions of 35 U.S.C. § 112, second paragraph. Thus, the Examiners objections based on §112, second paragraph are believed to be traversed.

New independent claim 71 has been crafted in light of the Examiners concerns and suggestions. As it recites almost all of the elements of similar base claim 1 it should be allowable for that reason, as well as for the additional recitations it contains. Applicants therefore respectfully request favorable consideration claims 1-6 and 10-71 under 35 U.S.C. § 112, second paragraph, in view of the above amendments and remarks.

The Rejections Under 35 U.S.C. §102(b)

Claims 1-7, 9-10, 14-17, 22 and 70 are rejected under 35 U.S.C. §102(b) as being anticipated by van Reis et al. (United States Patent No. 5,256,294) (hereinafter the '294 patent). In response to the Examiner's very thorough comments it should be noted at the outset that the existing independent claim within this group (claim 1) has been amended herein to address a variety of the Examiner's concerns as well as to ameliorate some structural and grammatical problems with the claims. Therefore Applicant requests reconsideration of the claims in light of these extensive amendments and claim additions. Given the analysis below, applicable at least in part to all of the other proffered anticipation rejections, the Examiner's remaining objections to the claims as amended are respectfully traversed.

The fundamental requirement necessary to maintain a rejection based on anticipation is that each and every element of the claimed invention must be disclosed in a single prior art reference or embodied in a single prior art device or practice. In re Spada, 911 F.2d 705, 15 U.S.P.Q.2d 1655 (Fed Cir. 1990); See also, Minnesota Min. & Mfg. Co. v. Johnson & Johnson Orthopedics, Inc., 976 F.2d 1559, 24 U.S.P.Q.2d (Fed Cir. 1992). Moreover, anticipation requires **both an identity of elements and identity of process**, this Van Reis et al., is incapable of providing. Tyler Refrigeration v. Kysor Indus. Corp., 777 F.2d 687, 227 U.S.P.Q.177 (Fed Cir. 1986); Kalman v Kimberly-Clark Corp., 713 F.2d 760 (Fed. Cir. 1983), cert denied, 465 U.S. 1026 (1984). As was stated by the 9th Circuit:

"Unless all of the same elements are found in exactly the same situation and united in the same way to perform the identical function in prior pleaded art, there is no anticipation." Stauffer v. Slenderella Systems of California, Inc., 254 F.2d 127, 115 USPQ 347 (9th Cir. 1957).

That is, for anticipation to be properly found it is necessary that a previous disclosure express the virtually identical presence and function of the claimed methods and assays, thereby putting the invention in the hands of the public to practice. In re Wilder, 429 F.2d 447, 166 USPQ 545 (C.C.P.A. 1964); In re Brown, 329 F.2d 1006, 141 USPQ 245 (C.C.P.A. 1964); In re LeGrice, 301 F.2d 929, 133 USPQ 365 (C.C.P.A. 1962). This is clearly not done with the Van Reis or the other cited reference used to anticipate the current claims. It should be noted that the current claims recite milk as a feedstream – van Reis does not.

Given the above, in order to avoid rejection for anticipation, it is only necessary to show that independent base claim 1 contains at least one element not disclosed in van Reis et al. In reviewing the teachings of the Van Reis reference, as guided by the prior legal precedent cited above, it is clear that the claims not only fail to recite the same elements, the actual function or "process" of utilizing the elements differs considerably. More to the point, amended claim 1 recites several elements not present or suggested in any of the teachings of Van Reis including:

- a) usage of milk as a feedstream;
- b) primary usage of ultrafiltration as opposed to microfiltration; and

Neither of the elements a or b above are disclosed in the van Reis reference. Therefore, it is respectfully proposed that the rejection of claim 1 for anticipation by the Van Reis reference is overcome.

Likewise, claim 71 recites several elements not present or suggested in any of the teachings of Van Reis including:

- c) cell lysate as a feedstream;

- d) primary usage of ultrafiltration as opposed to microfiltration;

Neither of the elements c or d above are disclosed in the van Reis reference. Therefore, it is respectfully proposed that the rejection of independent claims 1 and 71 for anticipation by the Van Reis reference are overcome.

Dependent claims 2-6 and 10-70 being dependent upon and further limiting independent claim 1, should also be allowable for those reason, as well as for the additional recitations they contain. Reconsideration of the rejection of amended claims 1-6 and 10-70 under 35 U.S.C. § 102(b), is respectfully requested. New claim 71 carries limitations similar to those found in independent claim 1. Applicants therefore respectfully request favorable consideration claims 1-6 and 10-71 under 35 U.S.C. § 102(b), in view of the above amendments and remarks.

The Rejection Under 35 U.S.C. §103(a)

van Reis et al and Kuniharu et al.

Dependent claims 12 and 13 are rejected under 35 U.S.C. §103(a) as being unpatentable over van Reis et al., in view of Kuniharu et al. In response to the Examiner's comments it should be noted at the outset that the existing independent claim has been amended herein to address a variety of the Examiner's concerns as well as to ameliorate some structural and grammatical problems with the claims. Therefore Applicant requests reconsideration of the claims in light of these extensive amendments and claim additions. Given the analysis below, the Examiner's remaining objections to the claims as amended are respectfully traversed.

Establishment of a *prima facie* case of obviousness is a procedural tool for allocating the burden of proof as between an Applicant and the Examiner. The initial burden is upon the Examiner to present this *prima facie* case of obviousness to negative patentability. Respectfully, in the current case the Examiner has failed to establish the needed case of obviousness, thus without more the Applicant is entitled to a grant of the patent. In re Oetiker, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992).

A *prima facie* case of obviousness is established when the teachings from the prior art itself suggest the claimed subject matter to a person of ordinary skill in the art.

In re Bell, 991 F.2d. 781, 26 U.S.P.Q. 1529 (Fed. Cir. 1993); In re Rijckaert, 28 U.S.P.Q.2d 1955 (Fed. Cir. 1993). The basic considerations which apply to obviousness rejections under MPEP § 2141 are as follows:

- (1) the claimed invention must be considered as a whole;
- (2) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (3) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and
- (4) reasonable expectation of success is the standard by which obviousness is determined.

When the prior art itself fails to meet even one of the above criteria the cited art does not satisfy 35 U.S.C. § 103(a) and prevents the establishment of the required *prima facie* case of obviousness by the Examiner. In re Oetiker, 977 F.2d 1443, 1445, 24 U.S.P.Q.2d 1443, 1444 (Fed. Cir. 1992); In re Rijckaert, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). As pointed out above, the van Reis reference not only fails to render obvious the current claims it also fails to provide any incentive to combine with other prior art for use in the an application wherein milk or cell lysate is the primary feedstream .

Moreover, if these failings are insufficient to disqualify the van Reis reference it should be noted that if the prior art methodology must be modified in any way to practice the instant invention the prior art citations must also render obvious these modifications or provide a reasonable expectation for the successful practice of the invention with the necessary modifications within the four corners of the references cited be the Examiner.

In addition it must be respectfully reiterated that each of the citations provided above fail to recognize, expressly or implicitly, any need, possibility or benefit of combining their disparate teachings in such a way that they might then read on the instant claims. Absent some teaching, suggestion, or incentive supporting this combination, a teaching that is simply not present in any of the citations provided by the Examiner, the references are incapable of supporting a obviousness rejection under § 103(a). Carella v. Starlight Archery, 231 U.S.P.Q. 644 (Fed. Cir. 1986).

Respectfully, it is thus the objective measure of obviousness that the prior art cited of record is incapable of supporting, thus preventing the maintenance of a 35 U.S.C. §103(a) rejection. Applicants therefore respectfully request the withdrawal of the Final Rejection of the amended claims 1-6 and 10-70 under 35 U.S.C. §103(a).

New claim 1 is independent but was crafted with the Examiner's concerns in mind and should be allowable for this reason, as well as for the additional recitation it contains. Applicants therefore respectfully request favorable consideration claims 1-6 and 10-71 under 35 U.S.C. § 103(a), in view of the above amendments and remarks.

Other than a fee for the extension of time, no fee is deemed necessary in connection with the filing of this Amendment after Final Rejection. However, the Commissioner is authorized to charge any fee which may now or hereafter be due for this application to GTC Biotherapeutics' Deposit Account No. 502092.

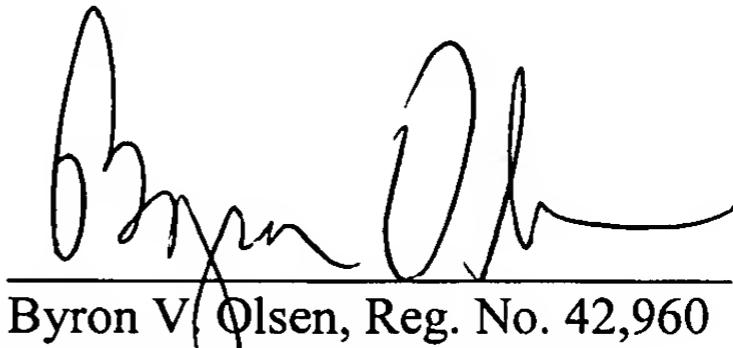
Applicants respectfully submit that the pending claims of this application are in condition for allowance, and that this case is now in condition for allowance of all claims therein. Such action is thus respectfully requested. If the Examiner disagrees, or believes for any other reason that direct contact with Applicant's attorney would advance the prosecution of the case to finality, the Examiner is invited to telephone the undersigned at the number given below.

Early and favorable action is earnestly solicited.

Respectfully Submitted,

Date: 9/23/04

By:



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Amendments to the Drawings:

The attached sheets of drawings include the addition of Figures 11-19.

Please add Figure 11, Graphs A-D.

Please add Figure 12, Graphs E-H.

Please add Figure 13, Graph I.

Please add Figure 14, Graph J.

Please add Figure 15, Graph K.

Please add Figure 16, Graph L.

Please add Figure 17, Graph M.

Please add Figure 18, Graph N.

Please add Figure 19, Graphs O & P.

Attachment: Replacement Sheets of Figures 1 – 19 (Figures 1-10 for sheet renumbering only).